



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Respectful Maternity Care:

Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Respectful Maternity Care: Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER
DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

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FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Center (EPC) Program to complete a review of the evidence for *Respectful Maternity Care: Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Respectful Maternity Care: Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/respectful-maternity-care/protocol>

This is to notify the public that the EPC Program would find the following information on Respectful Maternity Care: Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential, marketing materials, study types not included in the review, or information on indications not included in the review cannot be used by the EPC Program. This is a

voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ1. Which components of Respectful Maternity Care (RMC) have been examined using validated measures? Are there validated tools to measure RMC?

KQ2. What is the effectiveness of strategies to implement RMC?

KQ3. What is the effectiveness of RMCE on maternal health and utilization outcomes?

- a. How does effectiveness vary among disadvantaged pregnant persons?
- b. Which components of RMC are associated with effectiveness?
- c. Which (non-patient) factors are associated with effectiveness?

KQ4. What is the effectiveness of RMC on infant health outcomes?

- a. How does effectiveness vary among infants of disadvantaged pregnant persons?
- b. Which components of RMC are associated with effectiveness?
- c. Which (non-patient) factors are associated with effectiveness?

For KQ 3a and 4a, 'disadvantaged pregnant persons' may be defined by geography, race/ethnicity, age, disability, language, education, SES, etc., as described in Cochrane's PROGRESS-Plus framework.¹ In KQ 3c and 4c, 'non-patient factors' could be related to setting (type of hospital, rural/urban, staffing ratios) or intervention characteristics.

Contextual Question (CQ)

CQ1. How is RMC during labor and delivery, and the immediate postpartum period defined in the literature? Does the literature define the essential/critical components of RMC? For example, is teamwork and communication (amongst providers, staff, patients and families) an essential element of RMC?

PICOTS (Populations, Interventions, Comparators, Outcomes, and Settings)

	Inclusion	Exclusion
Population	KQ 1-4: Pregnant adolescents and adults admitted for labor through discharge after delivery <u>Subgroups of interest:</u> <ul style="list-style-type: none">KQ 3a and 4a: Disadvantaged individuals^a	Non-pregnant populations
Interventions	KQ 1: Validated measures of RMC KQ 2: Implementation strategies for RMC (eg, patient/provider education, policies, payment, doula/patient advocate, practice facilitation) KQ 3-4: RMC (any definition) KQ 3b and 4b: Specific component of RMC	Non-validated RMC measures
Comparators	KQ 1: Other tool(s), reference/gold standard or no tool to measure RMC KQ 2: Other implementation strategies for RMC KQ 3-4: Routine maternity care Absence of a specific RMC component	No tool, measure, or comparison
Outcomes	KQ 1: <ul style="list-style-type: none">RMC as measured by a validated tool KQ 2: <ul style="list-style-type: none">RMC provider knowledge and/or practicesRates of procedures and interventions KQ 3: <ul style="list-style-type: none">Health outcomes for pregnant persons<ul style="list-style-type: none">Maternal morbidityMaternal mortalityMental health outcomesFunction, quality of life, patient satisfaction using validated measuresMental health outcomes based on validated measures (eg, anxiety, depression)HarmsUtilization outcomes for pregnant persons<ul style="list-style-type: none">Length of stayHealthcare utilization post-dischargeRates of procedures KQ 4: <ul style="list-style-type: none">Health outcomes for infants<ul style="list-style-type: none">Infant morbidityInfant mortalityHarmsUtilization outcomes for infants<ul style="list-style-type: none">Length of stay	KQ4: Infant health outcomes >1 year

	○ Healthcare utilization post-discharge	
Timing	<ul style="list-style-type: none"> • Intervention: Admission for labor through discharge after delivery • Outcomes: from admission through one year postpartum 	Interventions: before labor, during prenatal care Outcomes: More than one year postpartum
Settings	<ul style="list-style-type: none"> • KQ1, CQ: All countries in a hospital or birthing facility setting (eg, birth centers) • KQ 2-4: hospital or birthing facility in US or US relevant countries • KQ 3c and 4c: hospital or birthing facility in US or US relevant countries 	Home births
Study designs and publication types	<ul style="list-style-type: none"> • KQ1-4: Trials (randomized and comparative nonrandomized), comparative observational studies 	KQ 1: Studies that do not describe psychometric properties/methods of determining validity of measures or components KQ2-4: Case reports, case series (or similar single-arm designs) Publication types: Conference abstracts or proceedings, editorials, letters, white papers, citations that have not been peer-reviewed, single site reports of multi-site studies

Abbreviations: CQ, contextual question; KQ, key question; RMC, respectful maternity care
“Disadvantaged persons” as defined by PROGRESS-plus framework¹

Reference

1. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol.* 2014 Jan;67(1):56-64. doi: 10.1016/j.jclinepi.2013.08.005. PMID: 24189091.

Dated: November 2, 2022

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